

**Notice of Allowability**

Application No.

10/588,295

Examiner

MICHELE JOIKE

Applicant(s)

CHARTRAIN ET AL.

Art Unit

1636

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--**

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 12/21/10.
2. ☒ The allowed claim(s) is/are 42-50 and 56-59.
3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some\* c) ☐ None of the:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\* Certified copies not received: \_\_\_\_\_.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

**THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
- (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
- 1) ☐ hereto or 2) ☐ to Paper No./Mail Date \_\_\_\_\_.
- (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date \_\_\_\_\_.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).**
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

**Attachment(s)**

- |  |  |
|--|--|
| 1. <input type="checkbox"/> Notice of References Cited (PTO-892)   | 5. <input type="checkbox"/> Notice of Informal Patent Application  |
| 2. <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 6. <input checked="" type="checkbox"/> Interview Summary (PTO-413),<br>Paper No./Mail Date <u>20110324</u> . |
| 3. <input type="checkbox"/> Information Disclosure Statements (PTO/SB/08),<br>Paper No./Mail Date _____    | 7. <input checked="" type="checkbox"/> Examiner's Amendment/Comment  |
| 4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit<br>of Biological Material | 8. <input type="checkbox"/> Examiner's Statement of Reasons for Allowance                                    |
|  | 9. <input type="checkbox"/> Other _____.   |

/Michele K. Joike/  
Primary Examiner, Art Unit 1636

### EXAMINER'S AMENDMENT

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Melissa Wenk on March 24, 2011.

In the claims:

42. A process for production of plasmid DNA comprising:  
(a) selecting a highly productive clonal subtype of a strain of *E. coli* transformed with a DNA plasmid comprising:  
(i) observing a phenotypic heterogeneity in a population of colonies generated by the transformed *E. coli*, and selecting as potentially highly productive clonal subtypes those colonies that represent a minor component of said phenotypic heterogeneity in said population of colonies;  
(ii) purifying said potentially highly productive clonal subtypes and determining the productivity of said purified, potentially highly productive clonal subtypes by measuring the plasmid copy number per cell; and,  
(iii) selecting as a highly productive clonal subtype a potentially highly productive clonal subtype that exhibits a higher plasmid copy number per cell in comparison to non-selected, transformed *E. coli* clonal subtypes of the same strain; and,  
(b) cultivating said highly productive clonal subtype with fed-batch fermentation in chemically-defined medium in a fermentation volume of greater than ~~about~~ 1000L, wherein said phenotypic heterogeneity is observed after the transformed *E. coli* is grown on blood agar at about 30 °C, and  
wherein the potentially highly productive clonal subtypes that represent the minor component of said phenotypic heterogeneity are gray colored-colonies while the major component of said phenotypic heterogeneity are white-colored colonies.

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47. The process of claim 42, wherein the process further comprises

- (a) duplicate plating the transformed *E. coli* on blood agar and an agar that does not contain blood products;
- (b) growing the *E. coli* at about 30 °C until distinct colonies are visible;
- (c) observing the gray colonies as the minor component of said phenotypic heterogeneity on the blood agar;
- (d) determining which colonies on the agar that does not contain blood products correspond to ~~of~~ the gray colonies on the blood agar; and
- (e) purifying said colonies from the agar that does not contain blood products that correspond to ~~of~~ the gray colonies on the blood agar, wherein said purified colonies are the potentially highly productive clonal subtypes.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MICHELE JOIKE whose telephone number is (571)272-5915. The examiner can normally be reached on M-F, 10:00-6:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on (571)272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michele K. Joike/  
Primary Examiner, Art Unit 1636

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